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Biotechnology Annual Report

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Report Highlights:

Transgenic seed varieties have been grown in Costa Rica since 1992 with all seeds being exported to other countries. Costa Rica has implemented legislation to regulate the import and cultivation of genetically engineered crops but there is currently no requirement that foods containing genetically engineered components be labeled. The Costa Rican National Biosafety Commission has not met since February of 2018 as a result of internal legal issues. According to sources familiar with the situation, new members have been selected and the Commission will be able to start meeting again regularly. The last event for seed reproduction (cotton) was approved in June of 2017.

Section I. Executive Summary:

Transgenic seed varieties have been grown in Costa Rica since 1992 with all seeds being exported to other countries. Costa Rica has implemented legislation to regulate the import and cultivation of genetically engineered crops. This legislation includes a labeling requirement for genetically engineered (GE) agricultural products but there is currently no requirement that foods containing biotech components be labeled.

At the beginning of 2013, in response to a request by Monsanto for approval to plant a new variety of genetically engineered corn (production would be for propagation and re-export of the seeds - not for commercial production), groups opposed to biotechnology became very active again. This resulted in widespread press coverage of this particular issue with discussions that lasted several weeks in the leading newspapers. Although the NTBC eventually approved Monsanto's request to plant the new corn variety, the environmental groups raised the issue to the Constitutional Court (Sala Cuarta). **Note:** Although the Monsanto corn variety has been approved, the company decided not to plant in Costa Rica at this time. **End Note.**

Two cases were raised before the Constitutional Court - one case filed by the environmentalist groups. In this case, the Court ruled against two points presented by the environmentalists and in favor of one point. Although the Court issued the ruling in September 2014, it issued the full document which includes the legal justification for the ruling at the end of June 2015. The second case was presented by the "Defensoría de los Habitantes", an "Ombudsman" institution in Costa Rica. This case was recently resolved with results generally in favor of biotechnology, since it was similar to the first case in some aspects. When the second case was presented, the Court accepted it for review and suspended the "final administrative act" of the NTBC. For practical purposes the court prevented the Commission from issuing new product registrations until the case was solved. The NTBC could review requests for registration and could continue to operate but it could not issue approvals until the case was resolved.

These actions were perceived as a major setback by companies involved in biotechnology activities in Costa Rica. Research, production activities and development plans were stopped as a result. An additional issue of concern, although with unclear legal results, is the decision of a large number of municipalities or local governments (74 out of a total of 81) to declare themselves "free of transgenics".

Earlier this year, a member of the National Biosafety Commission challenged the approval of a cotton event and took the case to the Constitutional Court. Although the Court did not cancel the approval of the event, the Court ruled that in the future, requests for approval will have to be made public so that the public is aware of different aspects related to the event under review by the Biosafety Commission.

Costa Rica signed the Cartagena Protocol on Biosafety in May 2000. However, the Protocol was not ratified by the Legislative Assembly until July 17, 2006. It was published in the Official Diary, "La Gaceta", on November 27, 2006, thus becoming law. Since then, Costa Rica has been working on the national regulatory framework necessary for the implementation of the Protocol. The Ministry of Agriculture (MAG) has taken steps to reach agreements with importers and grain consumers in order to comply with the protocol.

SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) **PRODUCT DEVELOPMENT:** Costa Rican researchers are working on the development of bananas resistant to black Sigatoka, bananas resistant to *Fusarium oxysporum*, and pineapples with a higher content of antioxidants. The GE pineapples obtained FDA approval at the end of 2016, although they are not currently being produced commercially in Costa Rica. The pineapples project suffered at least a year's delay because of problems related to the NTBC. As a result of different administrative issues, the NTBC resumed normal operations until late 2016. In February of 2018, the NTBC stopped meeting again because of the change in administration. The new Minister of Agriculture has selected the new members, and the NTBC is expected to resume its regular meeting schedule. The NTBC meets the first Wednesday of each month. Representatives of groups opposed to biotechnology regularly fail to show up at the meetings with the apparent intention of preventing a quorum. These representatives regularly object to, and obstruct the approval of new agricultural biotechnology events.

b) **COMMERCIAL PRODUCTION:** Costa Rica produces GE cottonseeds entirely for export to the United States. The seeds do not stay in the country for local consumption. An estimated 300 hectares were planted with biotechnology seeds in 2017, and about 200 hectares were planted in 2018. Area planted may decline again in 2019 in preparation for the introduction of a new cotton event. This area is planted in cotton for propagation of planting seeds for export to the United States. Area planted with biotechnology crops peaked at 1,697 ha. in 2009.

The events approved for seed production are Roundup Ready, Roundup Ready Flex, Bollgard, Bollgard II, WideStrike, Cry 1F, Bomoxinil, Liberty Link, Vip 3A and some combinations of the previous ones for cotton. For soybeans, only Roundup Ready has been planted in the past. The Costa Rican Government (CRG) has not received any requests to date for approval to plant transgenic varieties for human or animal food consumption in Costa Rica. According to industry sources, the procedures to obtain permissions from the CRG to plant GE varieties are straightforward and did not represent an obstacle to production in the past. However, as mentioned before, the process to register new products was halted in 2013 for legal reasons and has suffered from periodic delays because of legal challenges

and slow nomination of NTBC members. Companies involved in this business will increase or reduce their planted areas based on the expected demand for their products in the United States. A list of approved events can be found here: <http://cr.biosafetyclearinghouse.net/decisions.shtml>

c) EXPORTS: As indicated above, the only exports of GE products are cottonseeds that are propagated in the country for the specific purpose of exporting them back to the companies that supplied them.

d) IMPORTS: Costa Rica imports GE corn and soybeans from the United States for animal feed production, and a small volume of cotton for processing. Imports of GE organisms are limited to those indicated above from the United States. The same products (corn and soybeans) have been imported from Brazil and Argentina as well.

e) FOOD AID: The country is not a recipient of food aid and is not likely to become a food aid recipient in the near future.

f) TRADE BARRIERS: There are no biotechnology trade barriers that affect U.S. exports at this time. Costa Rica is a large importer of soybeans and corn (primarily yellow corn for animal feed production). Imports of processed products that may contain products of biotechnology are also an important segment of total agricultural products imported from the United States.

PART B: POLICY

a) REGULATORY FRAMEWORK: In 1990, Costa Rica created the National Technical Biosafety Commission (NTBC), which is attached to the Ministry of Agriculture by law (Plant Health Protection Law 7664 of April 1997, (see text in Spanish) [Phytosanitary Protection Law](#)). The law confers upon the NTBC power to regulate imports, exports, research, testing, movement, propagation, industrial production, marketing and use of transgenic and other genetically modified organisms for agricultural use.

In 2004, environmental groups strengthened their campaign against the planting of genetically engineered varieties in Costa Rica. That year, a coalition of such groups submitted a petition to impose a moratorium on the planting of genetically engineered varieties citing the “precautionary principle with respect to both the environmental impact and the human health impact of biotechnology”. That same year, a Presidential Decree was published modifying the composition of the National Technical Biosafety Commission (NTBC) which reviews all requests for approval of new genetically engineered varieties for planting or propagation. The NTBC now has two members from environmental groups and an additional member from the Ministry of the Environment (ME). The composition of the NTBC suffered changes under the previous Administration, which gave it a more political than scientific leaning. For instance, the ME Vice-Minister was a member of the NTBC for a while although she is a lawyer not a scientist by training. Also, the directors of the Plant and Animal Health Departments of the Ministry of Agriculture (who are both political appointees), have replaced scientists who previously held the positions.

The current NTBC is made up of one representative of the Science and Technology Ministry, two

representatives from the Ministry of Agriculture, two representatives from the Ministry of the Environment, one representative from the National Seeds Office, two representatives from the National Academy of Sciences, one representative from the Federation for Environmental Conservation, and one representative from the Biodiversity Conservation Network.

During the previous legislature, two political parties, the Citizen's Action Party (the governing party) and the Frente Amplio (a left wing party) supported a bill called, "Law of National Moratorium to the Liberation and Cultivation of Living Modified Organisms (transgenics)" (file number 18957). The Minister of Agriculture showed strong support for the bill during its review by the Agricultural Issues Committee of the Legislative Assembly. The bill was defeated in the Committee and did not reach the Plenary of the Assembly. An even more restrictive bill called, "Law for the Restriction of the Release into the Environment of Genetically Modified Organisms" (file number 19477), was also promoted and supported by the Executive although it was not approved either. The bill called for a 15-year biotech moratorium.

The country has specific legislation in place for the approval of plant biotechnology events for cultivation, import, and export. However, at this time there is no specific legislation requiring approval of products of biotechnology for food consumption, feed or processing. Imports of U.S. grains and soybeans for animal feed production enter Costa Rica under procedures identical to the importation of any other agricultural product.

- b) **APPROVALS:** Requests to obtain approval to plant a biotechnology crop (to be grown commercially, as a field trial, or to be grown for export purposes only) are evaluated by the NTBC. A list of approved events can be found here: <http://cr.biosafetyclearinghouse.net/decisions.shtml>
- c) **STACKED or PYRAMIDED EVENT APPROVALS:** Cases that present stacked events (plants that combine two, or more already approved traits, such as herbicide and insect tolerance) need to undergo the same risk evaluation process as the individual events.
- d) **FIELD TESTING:** The country allows field tests of biotechnology crops, following appropriate risk analysis for each particular case. At this time field testing underway is limited to a few hectares of pineapples and bananas.
- e) **INNOVATIVE BIOTECHNOLOGIES:** Costa Rica has not developed regulations for innovative biotechnologies. Government officials with regulatory responsibilities in the biotechnology field have held meetings to discuss the need for regulation of such biotechnologies but they acknowledge that it would involve political compromise by different government sectors (Ministry of Science and Technology, Ministry of the Environment and Energy, Ministry of Health, and Ministry of Agriculture and Livestock), which has not been possible at this point.
- f) **COEXISTENCE:** Regarding the coexistence of biotechnology and non-biotechnology crops (including organic agriculture), Executive Decree 29782 – MAG of September 18, 2000 (Organic Production Regulation), indicates in Chapter III, Article 24: "Genetically Engineered Organisms or those obtained through genetic engineering and the products derived from such organisms, are not compatible with the principles of organic production (understood as production, processing, manufacture or marketing), and their use in organic agriculture is not allowed". The link to the law can

be found in the following link under “Leyes” (see Ley 8591):

<http://www.sfe.go.cr/SitePages/Normativa/InicioNormativa.aspx>

Costa Rica has legislation in effect to promote the production of organic crops. Article 24 of the legislation indicates the following: “any person who plants transgenic products, will have to obtain permission from the Ministry of Agriculture, without which, the person will not be allowed to initiate the activity. The permit will be granted if there is a previous study proving that there is no organic production within a reasonable distance, which may be affected by wind or proximity. The procedure to grant the permit will include consultations by the authorities with the organic producer organizations present in the area.”

g) **LABELING:** There is no law regarding the use of labels such as “biotech free”, “non-biotech”, “gmo-free” or “non-gmo” right now. Anti-biotech as well as consumer protection groups are pushing for mandatory labeling of food products derived from modern biotechnology. Given the support against biotechnology from some political groups as mentioned in the Executive Summary, labeling legislation now has a higher chance of approval than in the past. According to government officials, an inter-agency commission is reviewing a draft regulation for the evaluation of the safety of genetically engineered products for human and/or animal consumption. The need to label genetically engineered products authorized for consumption will be considered after the draft regulation mentioned above is approved. At this time labeling is required to introduce and/or trade plant products or other genetically modified organisms (GMOs) for use in agriculture in Costa Rica. In this case the product must be identified as such on a label where the consumer can identify its characteristics. To date, this requirement has been applied only to labeling of planting seeds.

Environmentalists have called in the recent past for legislation to ban the import of transgenic grains and to establish a labeling system for transgenic foods. During 2017, Costa Rica imported \$252 million of biotech commodities from the United States, based on the value of corn and soybean imports. Processed food imports, many of which contain ingredients derived from biotech commodities, are also growing.

h) **MONITORING AND TESTING:** The country does not have monitoring program for GE products and does not actively test for GE products.

i) **LOW LEVEL PRESENCE POLICY:** Costa Rica does not have a Low Level Presence policy at this time.

j) **ADDITIONAL REGULATORY REQUIREMENTS:** There are no additional requirements beyond approval by the NTBC for plant biotechnology events.

k) **INTELLECTUAL PROPERTY RIGHTS (IPR):** Although the country currently does not plant GE crops commercially, there is legislation in effect that would protect intellectual property rights for such products.

l) **CARTAGENA PROTOCOL RATIFICATION:** Costa Rica signed the Cartagena Protocol on Biosafety in May 2000. The Protocol was ratified by the Legislative Assembly until July 17th, 2006. It was published in the Official Diary, “La Gaceta” on November 27th, 2006, thus becoming law. Costa

Rica has been working on the national regulatory framework necessary for the implementation of the Protocol. The Ministry of Agriculture (MAG) has taken steps to reach agreements with importers and grain users in order to comply with the protocol. As part of this process, the Ministry of Agriculture approached Post in the past to request a list of all agricultural biotechnology events approved by the United States.

m) **INTERNATIONAL TREATIES/FORA:** In general, Costa Rica has been an active participant in International Fora such as Codex Alimentarius. On different occasions, Costa Rica has shared or supported U.S. positions on many different issues related to biotechnology. Also, Costa Rica has participated in the meetings of the parties to the Cartagena Protocol after the country ratified the agreement.

n) **RELATED ISSUES:** Not applicable.

PART C: MARKETING

a) **PUBLIC/PRIVATE OPINIONS:** The anti-biotech campaign, created by different groups under the Federation for Environmental Conservation and the Biodiversity Conservation Network, did not have a significant negative impact among consumers in the past. However, because of the lack of scientific education of the public and the widespread use of misinformation by groups opposed to biotechnology, the perception and attitudes toward genetically engineered products may be changing amongst the general population. The general public has limited knowledge of the topic and can be easily influenced by these groups, especially in rural areas, where the educational level of the population tends to be lower. On the other side, these groups' statements and actions have given scientists, Ministry of Agriculture officials, and the press the opportunity to express points of view favorable to biotechnology.

Post noticed different activities organized by environmental groups in support of the biotech moratorium bill. For instance, in March 2016, an organization called "Pax Natura" brought to Costa Rica anti-biotech writer Steven M. Drucker who wrote, "Altered Genes, Twisted Truth", and world renowned primatologist Jane Goodall who wrote the prologue to the book. During their visit, they met with legislators to promote the moratorium bill. In addition, the left wing party "Frente Amplio" organized an event in June 2015 at the Legislative Assembly with the participation of Dr. Ray Siedler, a former Environmental Protection Agency researcher and vocal opponent to biotechnology. The number of activities organized by opponents of biotechnology declined in 2017 and 2018.

b) **MARKET ACCEPTANCE/STUDIES:** Costa Rica is an importer of corn and soybeans from the United States. There seems to be very little, if any, concern regarding the process from which these products are derived, among users (primarily animal feed producers) or among consumers in the country. The majority of the population is not aware that almost all the yellow corn and soybeans imported into the country for animal feed production is derived from biotech varieties. However, anti-biotech groups are trying to build a negative perception of such products among the public mostly through fear and misinformation.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

- a) **PRODUCT DEVELOPMENT:** There are no GE animals or clones of animals under development in the country at this time. The National Animal Health Service (SENASA) has received a request to use a genetically engineered *Aedes aegypti* mosquito for controlled release in areas affected by dengue fever, chikungunya, and the zika virus. The request is still under review.
- b) **COMMERCIAL PRODUCTION:** Costa Rica does not commercially produce any livestock clones or GE animals or products derived from animal biotechnologies.
- c) **EXPORTS:** The country does not export any GE animals, livestock clones, or products from these animals at this time.
- d) **IMPORTS:** Costa Rica has not imported GE animals or livestock clones or products from these animals.
- e) **TRADE BARRIERS:** There are no specific trade barriers to imports of genetically engineered products. Imports of any such products would have to go through the evaluation procedures established by the local authorities.

PART E: POLICY

- a) **REGULATORY FRAMEWORK:** Law #8495 (General Law of the National Animal Health Service) provides SENASA with the legal authority to regulate animal biotechnology in Costa Rica. The following is the link to the text of the law:

[SENASA Law \(English version\)](#)

SENASA also regulates issues related to food safety for animals and animal products, and animal welfare. Environmental safety issues are regulated by the Ministry of the Environment (MINAET). The field of animal biotechnology regulation is not as developed as plant biotechnology. The Ministry of Agriculture has yet to develop specific regulations for animal biotechnology, even though the General Law makes SENASA responsible for regulating this specific area of biotechnology.

According to SENASA, the regulatory process would involve different Ministries depending on the final use of the product. For instance, any animal product would have to be registered at SENASA first; if it is going to be liberated into the environment (for instance a GE mosquito), it would have to be registered with the Ministry of the Environment as well. If the product could influence human health, it would have to be registered with the Ministry of Health. Also an animal intended to be used for research purposes would have to be registered with the Ministry of Science and Technology to comply

with animal welfare regulations.

- b) **INNOVATIVE BIOTECHNOLOGIES:** Costa Rica has not developed regulations for innovative biotechnologies. Government officials with regulatory responsibilities in the biotechnology field have held meetings to discuss the need for regulation of innovative biotechnologies, but they acknowledge that the development of such regulations involves a political compromise of different Government sectors (Ministry of Science and Technology, Ministry of the Environment and Energy, Ministry of Health, and Ministry of Agriculture and Livestock), and such agreement has not been reached at this point.
- c) **LABELING AND TRACEABILITY:** Labeling regulations have not been developed for products of animal biotechnology. However, Article 69 of SENASA's Law indicates that any establishment that produces, imports, stores, transports or sells genetic or biotechnology materials of animal origin for human or animal consumption, must have those materials or animals properly identified, must identify the product using appropriate identification materials, must keep the information related to the origin of the animal or product, and must provide the information to SENASA for the operation of the traceability system. The country has traceability regulations in place for live animals, which would apply to GE animals in the eventual case of introduction into the country.
- d) **INTELLECTUAL PROPERTY RIGHTS (IPR):** There is legislation in effect that would protect intellectual property rights for such products.
- e) **INTERNATIONAL TREATIES/FORA:** Post is not aware of specific interventions by Costa Rican officials on the subject of animal biotechnology in international fora. The local Codex Alimentarius Committee is located at the Ministry of Economy. According to government representatives, local officials have not participated in animal biotechnology discussions under Codex or the OIE recently.
- f) **RELATED ISSUES:** Not applicable

PART F: MARKETING

- a) **PUBLIC/PRIVATE OPINIONS:** Please see the section on plant biotechnology.
- b) **MARKET ACCEPTANCE/STUDIES:** The information provided above on the subject of acceptance of plant biotechnology generally applies to animal biotechnology. However, the issue of animal biotechnology has not received much attention over the last few years in the local press. Post would expect the issue to be controversial if and when it becomes a public discussion topic.